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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/982,992

Applicant(s)

PATTI ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) 15-17, 19-21 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) 9-12, and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

HL

## **DETAILED ACTION**

### ***Amendment Entry***

1. The amendment filed September 24, 2005 has been entered. Claim 1 has been amended. Claim 22 has been cancelled. Claims 15-17, 19-21 and 27-29 have been withdrawn. Claims 1-14, 18 and 23-26 are under consideration.

2. A complete reply to the final rejection must include cancellation of nonelected or withdrawn claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Withdrawal of Rejections***

3. The following objections and rejections have been withdrawn in view of applicants' arguments:

a) The written description rejection of claims 1-14, 18 and 23-26 under 35 U.S.C. 112, first paragraph;

b) The enablement of claims 1-14, 18 and 23-26 under 35 U.S.C. 112, first paragraph; and

c) The rejection of claims 1-14, 18 and 23-26 under 35 U.S.C. 112, second paragraph.

***Response to Arguments***

4. Applicant's arguments filed September 24, 2004 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The rejection of claims 1-4, 13 and 24 under 35 U.S.C. 102(b) as being anticipated by Hook et al., (US Patent 5,648,240) is maintained for reasons already of record. The rejection was on the grounds that Hook et al., teach an isolated antibody that is capable of binding to the Map10 protein from *Staphylococcus aureus*.

Applicants assert that Hook et al., do not disclose or suggest the specific Map10 protein or antibodies that were capable of specifically binding to the protein. In response to applicant's argument that Hook et al., do not disclose or suggest the specific Map10 protein or antibodies that were capable of specifically binding to the protein, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, the claim language is drawn to an intended use, i.e., that the isolated antibody is capable of binding to the Map10 protein from *Staphylococcus aureus*. Therefore the capable of language is intended use language. The antibodies disclosed by Hook et al., teach a structure that is capable of performing the intended use of

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binding to the Map10 protein from *Staphylococcus aureus*. Thus, the intended use language has not been given patentable weight. Moreover the instant claims fail to recite any structural limitations that would distinguish the instant claims over the prior art. Therefore, Hook et al., teach the instant claims and applicants' arguments are not found persuasive.

Applicants assert that the antibodies disclosed by Hook et al., have not been shown to be useful in treating infection, unlike the instantly claimed antibodies. In response to applicant's argument that the Hook et al., reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., being useful in treating infection are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants' assert that the antibodies of Hook et al., are different than the instantly claimed antibody. Applicants' make broad generalization about antibodies raised to complete proteins and antibodies raised to smaller subregions of proteins and concludes that because there may be differences in the antibodies raised, there are differences between the instantly antibody and the antibody of the prior art.

It is noted that applicants' point to US Patent 6,288,214 for support of this generalized theory. However prosecution of other patents are conducted on a case-by-case basis. It is irrelevant to rely on an unrelated patent where the prosecution history is unknown. The instant case is deemed to be rejected under 35 U.S.C. 102(b) as being

anticipated by Hook et al., (US Patent 5,648,240). Applicants' have not provided, beyond the misplaced reliance on the other patents, evidence to refute the rejection. Thus the rejection is maintained.

With respect to the broad generalizations about antibody differences, it is noted that differences in antibody structure does not necessarily equate to the antibodies displaying different binding abilities. Hook et al., teach isolating the Map protein, which has approximately 95% sequence identity to the Map10 protein taught by applicant. Hook et al., teach antibodies that inhibit the binding of *S. aureus*, thus the antibodies of Hook et al., have the same capabilities as those instantly claimed. Moreover, applicants' specification at page 5 states that the Map10 region is the binding region for the whole Map protein. Therefore, if an antibody binds to the Map protein, it must bind to the Map10 region. Thus, Hook et al., antibodies that bind to the Map protein must also bind to the Map10 region, and antibodies of Hook et al., thereby meet the claimed limitations. Applicants' have provided no evidence that the variable binding regions on the antibody of Hook et al., is different than the antibody of the instant claims. Applicants' have made no argument that the protein of Hook et al., bears different epitopes or binding regions as compared to the peptide of the instant application or that an epitope mapping analysis comparing the antibody of the prior art to the antibody of the instant claims differs. Thus, applicants' statements without the provision of scientific evidence that the antibodies of Hook et al., are not capable of binding to the Map10 protein is not found persuasive.

Applicants assert that the antibodies disclosed by Hook et al., have not been shown to be useful in treating infection, unlike the instantly claimed antibodies. However, as previously stated the intended use of treating infections does not create patentable weight. Moreover, the improved results with regard to treatment of infection is not recited by the instant claims, therefore it is not a limitation that holds patentable weight. Therefore, applicants' assertions that this makes the antibodies different is irrelevant, since such distinctions are not instantly claimed. Hook et al., teach antibodies that inhibit the binding of *S. aureus*. The instant claim language fails to recite language that creates a structural difference between the prior art antibodies and the instant claimed antibodies. The difference in the treatment of infection does not equate to a different antibody, rather the improved treatment could be attributed to several factors such as the mode of administration, the use of particular reagents in conjunction with the antibodies or the effective amounts of antibody used.

Therefore applicants' arguments are not persuasive and the rejection is maintained.

### ***New Grounds of Objection and Rejection***

#### ***Claim Objections***

6. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Dependant claim 8 is not

further limiting because it refers to an antibody, which binds the MAP protein, and not to an antibody which binds the Map10 protein as required by claim 1. Clarification is required to overcome the objection.

### ***Specification***

7. The use of the trademarks such as QIAGEN<sup>TM</sup>, SIGMA<sup>TM</sup>, SEPHAROSE<sup>TM</sup> on pages 9,10 and 28 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "same specificity" in claim is a relative term which renders the claim indefinite. The term "same specificity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, the metes



and bounds of the term cannot be ascertained since there is no standard for determining the level of specificity needed. Therefore, clarification is required to overcome the rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 13-14 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Hook et al., (US Patent 5,648,240). The rejection of Hook et al., has been discussed above and in previous office actions, however Hook et al., is now being applied to additional claims.

Claim 13 is drawn to the antibody being polyclonal while claim 14 is drawn to isolated antisera. Example 7 teach that polyclonal antibodies were raised against the purified *S. aureus* (FDA 574). The retrieved antibodies meet the antisera limitation. Thus, Hook et al., teach a polyclonal antibody that is capable of binding to Map10 protein and antisera containing said antibodies, just as required by the claims.

Claim 24 is drawn to an antibody that has the ability to bind to an amino acid sequence coded by the nucleic acid sequence of SEQ ID NO;1 or degenerates thereof. Hook et al., teach the sequencing of the MHC-II-antigen like staphylococcal protein. Although the proteins have different names the proteins share sequence identity.,

therefore because of the high sequence identity between the proteins, antibodies which bind to the protein of Hook et al., will also bind to instantly claimed SEQ ID NO:1 or degenerates thereof. Thus the antibodies of Hook et al., will bind to an amino acid sequence coded by the nucleic acid sequence of SEQ ID NO:1 or degenerates thereof just as required by the instant claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 5-8 have rejected under 35 U.S.C. 103(a) as being unpatentable over Hook et al., (US Patent 5,648,240) in view of the instant specification via the incorporation by reference of the Hook et al., (US Patent 6,288,214). The claims are drawn to a monoclonal antibody which is a single chain antibody or selected from the group consisting of chimeric, humanized or human monoclonal antibodies. The claims are also drawn to an antibody fragment that has the same binding specificity of an antibody which binds to the MAP protein.

Hook et al., (5,648,240) has been previously discussed. However Hook et al., do not recite a monoclonal antibody which is a single chain antibody or selected from the group consisting of chimeric, humanized or human monoclonal antibodies or an

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antibody fragment that has the same binding specificity of an antibody which binds to the MAP protein.

The instant specification teach the term antibodies refers to polyclonal and monoclonal, chimeric, single chain, bispecific, simianized and humanized as well as Fab fragments such as those fragments which maintain the binding specificity of antibodies to MAP or Map10 proteins (page 14 [0032]).

Therefore, it would have been prima facie obvious at the time of applicants invention to modify the antibodies of Hook et al., ( '240) to prepare or characterize the antibodies as monoclonal single chain antibody, humanized antibodies or fragments that have the same binding specificity as taught by Hook et al., ('240) since such techniques are well known in the art. No more than routine skill would have been required to generate any of these types of antibodies or antibody fragments since such techniques are well known in the art. Moreover, one would have had a reasonable expectation of success in preparing or characterizing the claimed antibodies since such antibodies can be used in a wide variety of purposes and the creation of such antibodies is well within the skill of one of ordinary skill in the art.

***Allowable Subject Matter***


11. Claims 9-12 and 25-26 are allowed over the prior art.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines   
April 13, 2005